§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) by adding in the eighth sentence the number ''011722,'' after the number ''000010,''.

Dated: June 29, 1999.

George A. Mitchell,

Acting Deputy Director, Center for Veterinary Medicine.

[FR Doc. 99–20257 Filed 8–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Nystatin, Neomycin, Thiostrepton, and Triamcinolone Acetonide Ointment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of nystatin, neomycin, thiostrepton, and triamcinolone acetonide vanishing cream base ointment for topical management of dermatologic disorders of dogs and cats.

EFFECTIVE DATE: August 6, 1999.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–245 that provides for veterinary prescription use of Derma-Vet Cream (nystatin, neomycin, thiostrepton, and triamcinolone acetonide) for topical management of dermatologic disorders in dogs and cats characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated, or threatened by bacterial or candidal (*Candida albicans*) infections.

Med-Pharmex's ANADA 200–245 is approved as a generic copy of Solvay's NADA 96–676 for Panalog® Cream. The ANADA is approved as of June 7, 1999. The basis for approval is discussed in the freedom of information summary.

The regulation in § 524.1600a (21 CFR 524.1600a) does not designate which approvals are for petrolatum base products (ointments) and which are for vanishing cream base products (creams). The regulation in § 524.1600a(b) is amended at this time to designate the base of each sponsor's product and to reflect this approval.

In addition, due to enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988, the footnote concerning the National Academy of Sciences/National Research Council review is outdated. At this time, the footnote and the footnote references are removed.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1600a is amended by revising paragraph (b) and by removing the footnote of paragraphs (c)(1)(i), (c)(1)(ii), (c)(1)(iii), (c)(2)(i), and (c)(2)(ii) to read as follows:

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.

* * * * *

(b) *Sponsors.* For petrolatum base ointments see 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter. For vanishing cream base ointments see 051259 and 053501.

* * * * *

Dated: June 29, 1999

George A. Mitchell,

Acting Deputy Director, Center for Veterinary Medicine.

[FR Doc. 99–20254 Filed 8–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 8832]

RIN 1545–AT56

Exception From Supplemental Annuity Tax on Railroad Employers

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance to employers covered by the Railroad Retirement Tax Act. The Railroad Retirement Tax Act imposes a supplemental tax on those employers, at a rate determined by the Railroad Retirement Board, to fund the Railroad Retirement Board's supplemental annuity benefit. These regulations provide rules for applying the exception from the supplemental annuity tax with respect to employees covered by a supplemental pension plan established pursuant to a collective bargaining agreement and for applying a related excise tax with respect to employees for whom the exception applies.

DATES: *Effective Date:* These regulations are effective August 6, 1999.

Applicability Date: These regulations generally apply beginning on October 1, 1998, except as provided in § 31.3221–4(e)(2).

FOR FURTHER INFORMATION CONTACT: Linda S. F. Marshall, (202) 622–6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Employment Tax Regulations (26 CFR part 31) under section 3221(d). On September 23, 1998, a notice of proposed rulemaking was published in the **Federal Register** (63 FR 50819) under section 3221(d). The proposed